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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/089,658 | 07/22/2002 | Alvin Berger | 112843-044 | 6858 |

29157 7590 11/18/2004

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| EXAMINER | |
|---|---|
| BERKO, RETFORD O | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/089,658 | BERGER ET AL. | |
| | Examiner | Art Unit | |
| | Retford Berko | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/282002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

**Acknowledgement**: The Information Disclosure Statement and Preliminary Amendment both filed on March 28, 2002 is acknowledged.

### Status of Claims

Claims 1-25 are currently pending in the application following the amendment.

### Joint Inventors

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### Claim Rejections-Sec 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims1-2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mechoulam et al (US 5, 618, 955).

The claims are directed toward a therapeutic or nutritional composition for oral administration comprising a naturally occurring precursor that is metabolized to a compound having amndamide activity; the precursor comprises of long chain polyunsaturated fatty acid of

the 16-28 carbon atoms with 2-6 double bonds; and the precursor comprises a fatty acid that is arachidonic acid.

As in claims 1-2 and 5; Mechoulam et al (Patent '955) teaches a pharmaceutical composition comprising arachidonyletanolamide (anandamide) and derivatives--col 4, lin 1-15; (see abstract, col3, lin 60-65, col 7, lin 65 and col 10, lin 10-15).

Claims 1-2 and 5 are anticipated by Patent '955.

2. Claims 1, 5, 16, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Stordy et al (WO 96/37200).

The claims are directed towards a composition comprising The claims are directed toward a therapeutic or nutritional composition for oral administration comprising a naturally occurring precursor that is metabolized to a compound having anandamide activity; the precursor is docosahexaenoate; administering the composition for treating glaucoma.

As in the claims 1, 5, 16, 22 and 25; Stordy et al (WO '200) teaches a method of treating dyslexia, said method comprising administration of a pharmaceutical composition comprising docosahexanoic acid (abstract, page 1-2 and page 6).

Claims 1, 5, 16, 22 and 25 are anticipated by Patent WO '200.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 5 and 14-25 are rejected as unpatentable under 35 U.S.C. 103(a) over Mechoulam et al (US 5, 618, 955) in view of Stordy et al (WO 96/37200) further in view of the combination Makriyannis et al (US 5, 874, 459) and Kyle et al (WO 94/28913).

The claims are directed towards a composition comprising The claims are directed toward a therapeutic or nutritional composition for oral administration comprising a naturally occurring precursor that is metabolized to a compound having anandamide activity; the precursor is docosahexaenoate (DHA). The claims are further directed toward administering the composition for treating glaucoma and that the compound mediates its biological action by reacting with a CB receptor.

The claims are also directed toward a method of producing a nutritional or therapeutic composition for oral administration by obtaining naturally occurring precursor and preparing the composition including the precursor, treating an anandamide-mediated ailment (e.g. glaucoma).

The disclosure in Mechoulam et al (Patent '955) regarding a pharmaceutical composition comprising arachidonyletanolamide (anandamide) and derivatives were discussed above. Patent '955 discloses synthetically produced anadamide and derivatives, discloses biological activity of

anadamide such as antiemetic and antiglucoma activity and other ailments (abstract; col 3, lin 35-50 and col 4, lin 30-60).

Patent '955 does not teach a method of producing a nutritional or therapeutic composition comprising docosahexanoate or anandamide from naturally occurring source and does not teach a method of treating a patient with the composition to alleviate an ailment.

Stordy et al (WO '200) disclose a method of treating dyslexia using DHA (abstract, page 1 and page 2). According to Stordy, DHA is particularly important in the function of retinal rods and that DHA significantly improves dark adaptation, reading ability and behaviour in children (page 2, and page 3); however, Stordy provides no indication of whether the compound reacts with the CB recptors.

Makriyannis et al (Patent '459) disclose novel inhibitors of anandamide amidase, said inhibitors react with CB1 and CB2 receptors (abstract, col 2, lin 15-20 and col 7, lin 45-50). Patent '459 discloses that a therapeutically effective amount of the anandamide amidase inhibitorsis also an amount that results in a sufficiently high level of anadamide in an individual to cause physiological effects that result in stimulation of the CB receptors, thus stimulating other biological effects such as decreased nausea resulting from chemotherapy, sedation and increased appetite as well as relieving intra-occular pressure in glaucoma patients (col 5, lin 60-65, continuing to col 6, lin 1-5).

Kyle et al (WO '913) disclose the outstanding limitation in that Kyle et al disclose a method of treating patients suffering from neuro-degenerative ailments associated with DHA or arachidonate (ARA) deficiency (abstract and page 6 lin 1--30, continuing to page 7, lin 1-5). More importantly, Patent '317 discloses preparation of DHA and ARA oils from natural sources

and extracting such compounds from the biomass of cultivated microorganisms (page 8, lin 25 and page 21, lin 5-10). According to Kyle et al, the administration of DHA and ARA offer significant advantage over merely obtaining linolenic or linoleic acid from standard foods (page 25, lin 32).

One of ordinary skill would have been motivated to prepare a composition comprising DHA and ARA for administration to patients as disclosed by the prior art cited. One of ordinary skill would expect to alleviate symptoms of neuro-degenerative diseases in patients because Patent '459 has disclosed that effective amounts of long chain fatty acids that interact with CB receptors also intraocular pressure in glaucoma, stimulate analgesia and elicit anti-emetic activity by reacting with CB1 and CB2 receptors (Patent '459, col 5, lin 60-65, continuing to col 6, lin 1-5). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm. Examiner Berko has been assigned future prosecution of the application.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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